# 3M™ Steri-Drape™ Thyroid Drape



## Description

All-in-one procedure drape, with diamond shaped aperture, made of 3M™ Steri-Drape™ Absorbent Impervious Material creates a sterile field during thyroid surgery.

## Product Benefits

- Reliable 2-inch adhesive strips which secure the drape to the skin.
- Low linting (INDA IST 160.1-83).
- Meets flammability class 1 (CFR Title 16 Part 1610).
- Diamond shaped aperture for easy application in the neck area.

## Suggested Applications

- Thyroid surgery

## Ordering Information

| Catalog Number<br>Product Description<br>Size | Packaging | UPN | Minimum Order | Pricing Unit |
|---|---|---|---|---|
| **9051**<br>**3M™ Steri-Drape™ Thyroid Drape; 3M™ Absorbent impervious material, Adhesive diamond aperture.** | | | | |
| Overall: 72" x 124" (183cm x 315cm)<br>Aperture: 4-1/2" x 4-1/2" (12cm x 12cm) | 1 Each<br>15 Each/Box<br>2 Box/Case | 00707387560430<br>30707387560431<br>50707387560435 | 2 Box | Box |



3M

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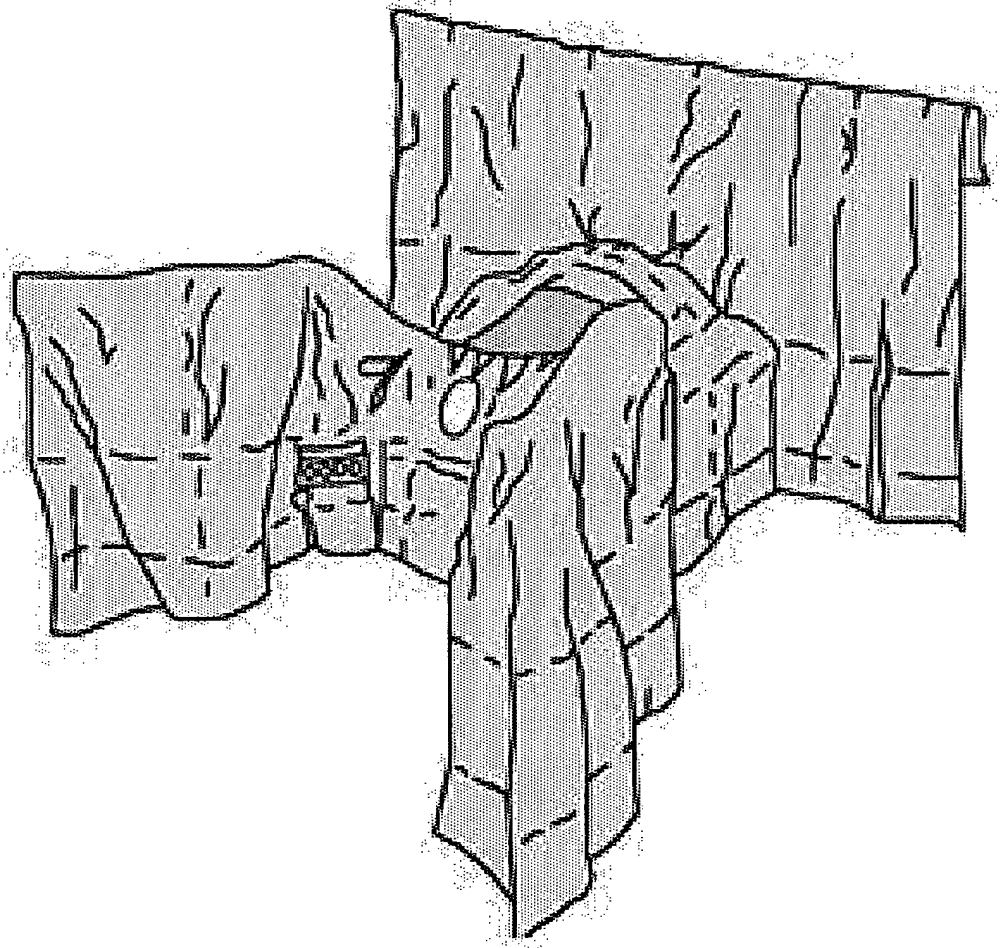
**In Canada, Contact** 1-800-563-2921


Faxable Doc 72456
July 2003

3M™ Steri-Drape™ (6665)

Overall Size

78"x 106" (200cm x 270cm)



3M™ Ioban™ 2 Antimicrobial incise area:

13" x 18" (35cm x 46cm)

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# 3M™ Ioban™ 2 Antimicrobial Incise Drapes

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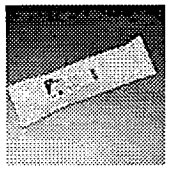

**Surgical drapes with an antimicrobial film designed to provide a sterile surface all the way to the wound edge and continuous antimicrobial activity throughout the procedure.**

[click to enlarge]

**Additional Information**

**Learn More . . .**

Fax Email Common Questions - Ioban 2 Antimicrobial Incise Drape - Questions and Answers (PDF 15.3 K)

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To help prevent surgical site infection, it is critical to reduce and restrict microorganisms from entering the open surgical wound. Ioban 2 antimicrobial incise drapes provide a sterile surface to the wound edge and continuous antimicrobial activity throughout the procedure. Ioban 2 film helps reduce the risk of surgical site contamination due to skin flora by providing a physical barrier

- **Biomedical Electrodes**
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- **Surgical Clippers and Prepping Solutions**
- **Surgical Drapes**
- **Wound Closure Products**

Full Text . . .

**Benefits**

- Ioban 2 incise drapes provide continuous broad-spectrum antimicrobial activity to help reduce the risk of surgical site contamination.
- The drape adheres securely to wound edges, providing a reliable barrier to bacteria on the skin.
- Incise drapes are made with a "low memory" film that conforms to body contours and stretches to allow limb manipulation.
- Available in a variety of sizes to meet your procedural and incision-size needs.
- Includes the "easy-delivery" drape application feature (except 6635).

**Make a Selection**

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6635

Incise area 3-7/8 inch x 7-7/8 inch (10cm x 20cm) Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6640EZ

Incise area 13 inch x 13 inch (35cm x 35cm) Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6648EZ

Incise area 23 inch x 23 inch (60cm x 60cm) Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6650EZ

Incise area 23 inch x 17 inch (60cm x 45cm) Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6651EZ

Incise area 23 inch x 33 inch (60cm x 85cm) Antimicrobial Incise Drape

-->

# 3M™ Ioban™ 2 Antimicrobial Incise Drapes

**Surgical drapes with an antimicrobial film designed to provide a sterile surface all the way to the wound edge and continuous antimicrobial activity throughout the procedure.**

[click to enlarge]

**Additional Information**

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Full Text . . .

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- The drape adheres securely to wound edges, providing a reliable barrier to bacteria on the skin.
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**Make a Selection**

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## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6648EZ

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## 3M™ Ioban™ 2 Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6650EZ

Incise area 23 inch x 17 inch (60cm x 45cm) Antimicrobial Incise Drape

## 3M™ Ioban™ 2 Antimicrobial Incise Drape 6651EZ

Incise area 23 inch x 33 inch (60cm x 85cm) Antimicrobial Incise Drape

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# 3M™ Steri-Drape™ Abdominal Perineal Drapes

**All-in-one procedure drapes designed to create a sterile field during abdominal-perineal procedures.**

**Additional Information**

These all-in-one procedure drapes make quick draping convenient by eliminating the need for multiple drapes. One person application of the perineal and abdominal sections.

**Learn More . . .**

Fax Email Steri-Drape Abdominal-Perineal Drapes - Catalog (PDF 53.3 K)

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The 6665 has 3M™ Ioban™ 2 Antimicrobial Incise Film, which creates a sterile antimicrobial surface. The 2065 has 3M™ Steri-Drape™ 2 Incise Film, which creates a sterile surface. The 1032 does not have any incise

Full Text . . .

**Benefits**

- One piece design makes draping quick and convenient by eliminating the need for multiple drapes and towels for the perineal area.

  Incise film:

  - Film provides a sterile operative surface to the wound edge at the start of surgery to help reduce the risk of surgical site contamination (2065, 6665).
  - Incise drape adheres securely to wound edges, providing a reliable barrier to bacteria on the skin.
  - Flexible, breathable film is extra conformable for easy application, even around difficult anatomical contours.
  - Ioban 2 incise film provides continuous broad-spectrum antimicrobial activity to help reduce the risk of surgical site contamination.

**Make a Selection**

## 3M™ Steri-Drape™ Abdominal-Perineal Drapes 2065

77 inches x 106 inches (195cm x 270cm) Abdominal-Perineal Drape with Incise film, Lithotomy position, 3M™ Absorbent Impervious Material, Perineal/vaginal aperture, Tube and cord organizers, Incise area 16 inches x 17-1/2 inches

## 3M™ Steri-Drape™ Abdominal-Perineal Drapes 6665

78 inches x 106 inches (200cm x 270cm) Ioban™ 2 Abdominal-Perineal Drape, Lithotomy Position, 3M™ Blue Fabric, Perineal/vaginal aperture, Tube and cord organizers, Incise area Ioban™ 13-5/8 inches x 18 inches (35cm x 46cm)

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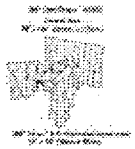
# 3M™ Steri-Drape™ Abdominal-Perineal Drapes 6665



**78 inches x 106 inches (200cm x 270cm) Ioban™ 2 Abdominal-Perineal Drape, Lithotomy Position, 3M™ Blue Fabric, Perineal/vaginal aperture, Tube and cord organizers, Incise area Ioban™ 13-5/8 inches x 18 inches (35cm x 46cm)**

[click to enlarge]

**Additional Information**

All-in-one procedure drapes designed to create a sterile field during abdominal-perineal procedures.

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# 3M™ Steri-Drape™ Thyroid Drape

Printer-friendly format

**All-in-one procedure drape, with diamond shaped aperture, made of 3M™ Steri-Drape™ Absorbent Impervious Material creates a sterile field during thyroid surgery.**

## Additional Information

3M™ Steri-Drape™ Absorbent Impervious Material creates a barrier to inhibit fluid strike-through reducing the need for extra drapes . . . less draping means less time in application and removal and fewer drapes to dispose of, saving time and money.

**Learn More . . .**

Fax Email Steri-Drape Thyroid Drape - Catalog (PDF 48.6 K)

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- **Surgical Drapes**
- **Wound Closure Products**

**Benefits**

- Reliable 2-inch adhesive strips which secure the drape to the skin.
- Low linting (INDA IST 160.1-83).
- Meets flammability class 1 (CFR Title 16 Part 1610).
- Diamond shaped aperture for easy application in the neck area.

**Make a Selection**

## 3M™ Steri-Drape™ Thyroid Drape 9051

72 inches x 124 inches (183cm x 315cm) Thyroid Drape, 3M™ Absorbent impervious material, Adhesive diamond aperture, Aperture 4-1/2 inches x 4-1/2 inches (12cm x 12cm)

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# 3M™ Steri-Drape™ Arthroscopy Drapes

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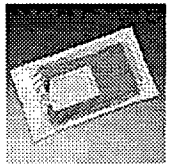

**Surgical drape sheets with a low-profile, roomy pouch to collect fluids flowing from the operative site during arthroscopic surgery. Available with one or two exit ports for drainage.**

[click to enlarge]

## Additional Information

The arthroscopy sheets are available alone, in a standard pack, or in custom trays. For custom tray availability, contact your 3M-authorized custom kit assembler.

**Learn More . . .**

Fax Email Common Questions - Steri-Drape Arthroscopy Drapes - Questions and Answers (PDF 15.6 K)

Fax Email Steri-Drape Arthroscopy Drapes - Catalog (PDF 54.3 K)

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## Benefits

- **Biomedical Electrodes**
- **Casting and Splinting Products**
- **Consumer Health Care Products**
- **Electrosurgical Pads**
- **Personal Protection Products**
- **Single-Use Clinical Thermometers**
- **Skin Health Products**
- **Sterilization Assurance Products**
- **Stethoscopes and Stethoscope Accessories**
- **Surgical Clippers and Prepping Solutions**
- **Surgical Drapes**
- **Wound Closure Products**

- Fluid control pouch collects and contains fluids to help keep patient and bed dry, and to help minimize the risk of body fluid exposure to healthcare personnel.
- Fluid control pouch attached to drape for easy, one-drape application to save time and money.
- Arthroscopy sheets are available individually, in a standard pack, or in custom trays to meet your institution's needs.
- 1194 sheet with pouch and 1007 pouch offer dual apertures that help with effective fluid collection for multiple knee positions.
- 1007 and 1067 pouch is useful as an add-on pouch to your current draping system.

**Make a Selection**

## 3M™ Steri-Drape™ Arthroscopy Fluid Collection Pouch 1007

Arthroscopy Fluid Collection Pouch; Clear plastic, Adhesive strips, Exit port, Overall Size: 46 inch x 22 inch (118cm x 58cm).

## 3M™ Steri-Drape™ Arthroscopy Pack 1095

Arthroscopy Pack; 1094 Arthroscopy Sheet with Pouch; 1019 Long U-drape; Impervious stockinette; 3M™ Coban™ self-adherent wrap, Mayo stand cover, Back table cover.

## 3M™ Steri-Drape™ Arthroscopy Pack 1195

Arthroscopy Pack includes: 1194 Arthroscopy Sheet with Pouch; 1019 Long U-drape; Impervious stockinette, 3M™ Coban™ self-adherent wrap, Mayo stand cover, Back table cover.

## 3M™ Steri-Drape™ Arthroscopy Sheet with Fluid Collection Pouch 1094

Arthroscopy Sheet with Fluid Collection Pouch; 3M™ Absorbent

Impervious Material, Exit port, tube and cord organizer, Overall Size: 89 inch x 125 inch (226cm x 320cm).

## 3M™ Steri-Drape™ Arthroscopy Sheet with Fluid Collection Pouch 1194

Arthroscopy Sheet with Fluid Collection Pouch; 3M™ Absorbent Impervious Material, 2 Exit ports, Tube and cord organizer, Overall Size: 89 inch x 120 inch (226cm x 304cm)

## 3M™ Steri-Drape™ Shoulder Split Sheet with Pouch 9196

Shoulder Split Sheet with Pouch; 3M™ Absorbent Impervious Material, Fluid collection pouch with 2 Exit ports, Overall size: 90 inches x 102 inches (228cm x 260cm)

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# Surgery in a Blanket



## Reference

Kurz, A., Sessler, D. I., and Lenhardt, R. (1996). "Perioperative Normothermia to Reduce the Incidence of Surgical-Wound Infection and Shorten Hospitalization," *The New England Journal of Medicine,* 334 (19), 2109-2115.

Frank, S., Fleisher, L., Breslow, M., Higgins, M., Olson, K., Kelly, S., and Beattie, C., (1997). "Perioperative Maintenance of Normothermia Reduces the Incidence of Morbid Cardiac Events," *Journal of the American Medical Association,* 277 (14), 1127-1134.

## Story

When patients undergo surgery, the operating room is kept cool so that the physicians in heavy gowns will not be overheated. The price for the surgeons' comfort could be paid by the patient. The exposure to cold, in addition to impairment of temperature regulation caused by anesthesia and altered distribution of body heat, may result in mild perioperative hypothermia (approximately 2°C below the normal core body temperature). As a result of the hypothermia, patients may have an increased susceptibility to perioperative wound infections or even morbid cardiac events.

In Austria, Kurz, Sessler, and Lenhardt (1996) investigated whether maintaining a patient's body temperature close to normal by heating the patient during surgery decreases wound infection rates. In a separate study at Johns Hopkins, Frank, et al. (1997) examined whether maintaining a patient's body temperature close to normal during surgery is associated with fewer incidents of (morbid) heart attack.

[TOP]

**Protocol: Austrian study**

Researchers Kurz, Sessler, and Lenhardt (1996) used the following protocol for their study:

All patients included in the study were undergoing colon or rectal surgeries, which are typically associated with a high risk of infection. The night before surgery, all patients were prepared for the next day's surgery in a standard manner. Both during and after surgery patients were given liquids intravenously in hopes that this would decrease the chance of infection caused by bacteria from the wound entering the bloodstream. Random assignment of patients to the temperature management groups was done during the induction of anesthesia. Codes which had been generated by computer and numbered and sealed in opaque envelopes were used for the random assignments. The two groups were the normothermic group (patients' core temperatures were maintained at near normal 36.5°C) and the hypothermic group (patients' core temperatures were allowed to decrease to about 34.5°C). While intravenous fluids were administered through a fluid warmer machine for both groups, only the normothermic group had the warmers activated. Additionally, a forced-air cover was used on the upper bodies of patients in both groups, but it delivered heated air in the normothermic group only (it delivered surrounding air in the hypothermic group). In order to keep the surgeons and operating room personnel from detecting which patient was in which group, shields and drapes were placed over all devices which would indicate group assignment. Postoperatively there was no controlling of patient temperatures, and the patients did not know their group assignments. All patients were able to self-administer pain killers.

Determinations of when to begin postoperative feeding, suture removal, and hospital discharge were made by attending surgeons who were unaware of the patients'; group assignments and core temperatures during surgery. Routine surgical considerations were involved in the discharge decisions. Note that the study was done in Austria, a country with managed health care, so that there are no insurance or administrative issues that might contribute to patient-to-patient variation in the length of stay at the hospital.

[TOP]

**Protocol: Johns Hopkins study**

The subjects in the study were 300 patients undergoing abdominal, thoracic, or vascular surgery, who either had documented coronary artery disease or were at high risk for coronary disease. These patients were randomly assigned to receive routine thermal care (hypothermic care) or normothermic care. According to Frank, et al. (1997),

...routine thermal care. . . was delivered according to the following protocol. The thermostat in the operating room was set to approximately 21°C. Intravenous fluids and blood were warmed [with the same type of device]. A [specific] heat-moisture exchanger. . . was used in the respiratory circuit for patients receiving general anesthesia. Intraoperatively, the patient was covered above and below the field [i.e., location of surgery] with one layer of paper surgical drapes. Postoperatively, either one or two warmed cotton blankets were placed over the patient, at the nurse's discretion.

Patients in the normothermic group were treated as follows. . . . The thermostat in the operating room was set to approximately 21°C, fluids and blood were warmed, and a heat-moisture exchanger was used in the respiratory circuit. Depending on the surgical site, an upper- or lower-body forced-air warming cover was placed over the patient. During the intraoperative and postoperative periods, both the temperature and airflow settings were adjusted to maintain core temperature at or near 37°C.

Since temperature was monitored via probes on the arm and fingertips during the postoperative period, the forced-air blanket was placed over the patient's legs and trunk, leaving the monitored arm exposed.

[TOP]

**Results**

**Austrian Study**

The following are excerpts from tables which were included in the Kurz, Sessler, and Lenhardt (1996) paper. For categorical variables, the tables give the number (and/or percent) of patients; for numerical variables, the tables give the mean ± (plus or minus) one standard deviation.

**Table 1: Characteristics of the Patients in the Two Study Groups**

| Characteristic | Normothermia (N = 104) | Hypothermia (N = 96) |
|---|---|---|
| Male sex (# patients) | 58 | 50 |

| | | |
|---|---|---|
| Weight (kg) | 73±14 | 71±14 |
| Height (cm) | 170±9 | 169±9 |
| Age (yr) | 61±15 | 59±14 |
| History of Smoking (# patients) | 33 | 29 |
| Diagnosis (# patients) | | |
| Inflammatory bowel disease | 10 | 8 |
| Cancer | 94 | 88 |
| Operative site | | |
| Colon | 59 | 51 |
| Rectum | 35 | 37 |
| Preoperative variables | | |
| Core temperature (°C) | 36.8±0.4 | 36.7±0.4 |
| Hemoglobin (g/dl) | 12.6±2.3 | 12.7±2.0 |
| Intraoperative Variables | | |
| Arterial blood pressure (mm Hg) | 91±17 | 95±18 |
| Heart rate (beats/min) | 74±17 | 76±13 |
| Red-cell transfusion (# patients) | 23 | 34 |
| Volume of blood transfused (units) | 0.4±1.0 | 0.8±1.2 |
| Urine output (liters) | 0.6±0.4 | 0.7±0.4 |
| Duration of surgery (hr) | 3.1±1.0 | 3.1±0.9 |
| Ambient temperature (°C) | 21.9±1.2 | 22.1±0.9 |
| Final core temperature (°C) | 36.6±0.5 | 34.7±0.6 |

| Postoperative variables | | |
|---|---|---|
| Hemoglobin (g/dl) | 11.7±1.9 | 11.6±1.4 |
| Prophylactic antibiotics (days) | 3.7±1.9 | 3.6±1.4 |
| Infection rate predicted by NNISS * (%) | 8.9 | 8.8 |
| Oxyhemoglobin saturation (%) | 98±1 | 98±1 |
| Piritramide (mg) | 20±13 | 22±12 |

*Note: NNISS is the National Nosocomial Infection Surveillance System. For our purposes, we need only to understand that this is a system which allows us to predict an infection rate (as in the above table) based on certain characteristics of the patient.

[TOP]

## Table 2: Postoperative Findings in the Two Study Groups

| Variable | Normothermia (N = 104) | Hypothermia (N = 96) |
|---|---|---|
| **All patients** | | |
| Infection - # patients (%) | 6 (6%) | 18 (19%) |
| ASEPSIS score | 7±10 | 13±16 |
| Collagen deposition - µg/cm | 328±135 | 254±114 |
| Days to first solid food | 5.6±2.5 | 6.5±2.0 |
| Days to suture removal | 9.8±2.9 | 10.9±1.9 |
| Days of hospitalization | 12.1±4.4 | 14.7±6.5 |
| **Uninfected patients** | | |

| | | |
|---|---|---|
| # patients | 98 | 78 |
| Days to first solid food | 5.2±1.6 | 6.1±1.6 |
| Days to suture removal | 9.6±2.6 | 10.6±1.6 |
| Days of hospitalization | 11.8±4.1 | 13.5±4.5 |

[TOP]

**Table 3: Postoperative Findings in the Study - Patients According to Smoking Status**

| Variable | Smokers (N = 62) | Nonsmokers (N = 138) |
|---|---|---|
| Infection - # patients (%) | 14 (23%) | 10 (7%) |
| ASEPSIS score | 15±18 | 8±10 |
| Days to suture removal | 10.9±3.5 | 10.1±2.0 |
| Days of hospitalization | 14.9±6.7 | 12.9±5.0 |

## Results

### Johns Hopkins Study

The following are excepts from tables which appeared in the Frank, et al. (1997) paper. For categorical variables, the tables give counts and percentages; for continuous variables, the tables give mean ± one standard error for the mean.

| | Intraoperative Cardiac Outcomes | |
|---|---|---|
| | Count (%) | |
| | Hypothermic (n=158) | Normothermic (n=142) |
| Event (Myocardial ischemia or ventricular tachycardia) | 15 (10%) | 13 (9%) |

| | Postoperative Cardiac Outcomes | |
|---|---|---|
| | Count (%) | |
| | Hypothermic (n=140) | Normothermic (n=123) |
| Event (ECG Event) | 23 (16%) | 9 (7%) |
| Event (Morbid Cardiac Event) | 33 (21%) | 11 (8%) |

| | Intraoperative Patient Characteristics | |
|---|---|---|
| | Mean ± S.E.M. | |
| | Hypothermic (n=158) | Normothermic (n=142) |
| Duration of surgery (hours) | 3.4 ± 1.1 | 3.6 ± 0.9 |
| Estimated blood loss (mL) | 520 ± 60 | 390 ± 70 |
| Crystalloid (mL) | 3200 ± 160 | 3000 ± 150 |

[TOP]

## Questions

### Question 1)

**a)** Was the *New England Journal* study

(i) a designed, controlled experiment or
(ii) an observational study?

Explain.

**b)** Which of the following might introduce bias into this study? Explain your choice.

(i). One surgeon performs all surgeries on the normothermic group while another performs all surgeries on the hypothermic group.

(ii). For each patient, a fair coin is tossed to determine which surgeon will operate on the patient.

**c)** Why did the researchers use double-blinding in this study?

**Question 2)** Review the protocol of the Johns Hopkins study.

**a)** What variables or (heating) factors are controlled in the Johns Hopkins study?

**b)** Which factors differ between the treatment and control groups in the Johns Hopkins study?

**c)** The protocol allows for patients in the control group to be given either one or two warmed cotton blankets, at the nurse's discretion. Explain why the researchers may have chosen to allow such subjectivity in the protocol of the study.

**Question 3)** One of the main points in the article by Kurz, Sessler, and Lenhardt (1996) was that the warming blankets (along with the other warming strategies), used for the normothermic group to keep them at or near normal body temperature during surgery, reduced the chance of infection. One effect of this would be that the patients in the normothermic group (the warming group) should have shorter hospital stays than those in the hypothermic group. To examine this, do the following:

**a)** Using the data from Table 2, perform an appropriate significance test for determining whether the treatment (use of warming blankets) affects prevalence of postoperative infection.

**b)** Using the data for *all patients* from Table 2, construct a 95% confidence interval for the difference between the means for length of stay in the hospital for the normothermia and hypothermic groups. What does this interval tell you about the effect of the treatment?

**c)** One might conclude, based on the results found in Parts a and b, that the use of warming blankets during surgery reduces infection rates and, therefore, decreases length of stay in the hospital. However, the use of the warming blanket might decrease length of stay for some reason unrelated to infection. Using the data from Table 2, carry out the significance test to determine whether the treatment affects length of stay for uninfected patients. Compute the test statistic, find the p-value, and state your conclusions.

**Question 4)** In the Results section for the Johns Hopkins study, the table of intraoperative patient characteristics gives the mean plus or minus (±) the standard error of the mean for various characteristics.

After reviewing that table, several students from an introductory Statistics class engage in the following debate. Evaluate their comments and decide which, if any, of the arguments are correct.

Student 1: About 95% of the surgeries for patients in the hypothermic group lasted between 1.2 and 5.6 hours. In the normothermic group, about 95% of the surgeries lasted between 1.8 and 5.4 hours.

Student 2: A 95% confidence interval for the mean duration of surgery for hypothermic patients is $3.4 \pm \frac{1.1}{\sqrt{158}} = (3.31, 3.49)$. For normothermic patients the interval is $3.6 \pm \frac{0.9}{\sqrt{142}} = (3.52, 3.68)$.

Student 3: The standard error for the mean seems unusually large, since the standard deviation for the individual observations is equal to the standard error of the means multiplied by the square root of n. Thus the mean plus or minus (±) one standard deviation would go far outside the range of possible values for duration of surgery.

**Question 5)** Kurz, Sessler, and Lenhardt (1996) stated that "those who smoked had three times more surgical-wound infections and significantly longer hospitalizations than the nonsmokers."

**a)** What do you think the researchers are referring to?

**b)** The hypothermic group had three times more infections than the normothermic group. Do you think, therefore, that smoking (rather than the treatment) may be the reason for the difference in the number of infections between the normothermic and hypothermic groups?

**Question 6)** Why did the researchers choose to make all of the comparisons listed in Table 1?

**Question 7)** Recall that the patients studied by Kurz, Sessler, and Lenhardt (1996) were adults undergoing colon or rectal surgery. Do the results we find in this data carry over to:

- other types of surgeries?
- shorter/longer surgeries?
- surgeries on children?

[TOP]

**Definitions**

perioperative: around the time of surgery

hypothermia: abnormally low body temperature

morbid: pertaining to, arising from, or affected by disease.

psychosomatic: relating to a disorder having physical symptoms but originating from mental or emotional causes.

Normal body temperature is around 37.0°C (98.6°F)

[TOP]

**Credits**

Thanks to Rusch International for supplying a picture of their surgical blanket.

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# In Vivo Study of an Antimicrobial Surgical Drape System

JULIUS CONN, JR.,[1]† JOHN W. BORNHOEFT,[2]* CAROL ALMGREN,[1] DAVID P. MUCHA,[3] JERRY OLDERMAN,[4] KANTIBHAI PATEL,[1] AND CRAIG M. HERRING[5]

*Department of Surgery, Northwestern University Medical School, Chicago, Illinois 60611[1]; J. W. B. Associates, Elmhurst, Illinois 60126[2]; Travenol Laboratories, Inc., Round Lake, Illinois 60073[3]; American Pharmaseal Company, Valencia, California 91355-8900[4]; and ISOMEDIX, Inc., Whippany, New Jersey 07981[5]*

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**We performed a double-blind clinical study to determine the efficacy of nonwoven laparotomy drapes in which 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride, an antimicrobial agent, was chemically bonded to the absorbent reinforcement surrounding the fenestration. The reinforcement portion of the surgical drape that contained the fenestration was segmented into four identical-appearing sections, two on each side of the fenestration. One segment on each side was antimicrobial. The locations of the treated segments were randomly varied. At the end of each operation, test strips were removed. Bacteria were harvested from each segment by mechanical agitation. Bacterial CFU were counted. There were 110 surgical cases in the study, including clean, clean contaminated, and contaminated procedures. Data analysis divided the cases into two distinct groups. Group 1 was composed of 59 cases in which less than 30 total CFU was recovered from the four test samples. The average duration of surgery for this group was 1.8 h. Group 2 was composed of 51 cases in which bacterial recovery was in excess of 30 CFU per procedure (range, 30 to 25,000 bacterial CFU). The average duration of surgery was 3.3 h. Bacterial reduction in the treated strips was 84%. The most common organisms identified on the laparotomy drapes were *Staphylococcus epidermidis*, *S. hominis*, and *Micrococcus luteus*. This study demonstrated that the reinforcement of a laparotomy drape is a reservoir for potential pathogens. It demonstrated that an organosilicon quaternary ammonium antimicrobial agent covalently bonded to the reinforcement reduced the number of potential pathogens surrounding the surgical incision by 84%, independent of the size of the bacterial challenge.**

It has been estimated that 30,000 to 60,000 organisms are deposited on a 3- to 4-$m^2$ sterile field during every hour of major operations. In a recent 2-year study of 15,207 patients admitted to a hospital, there were 1,851 nosocomial infections reported, for an infection rate of 12.8%. Postoperative wound infections were the most common nosocomial infections encountered in the surgical services during this study. They accounted for one-third to one-half of all of the infections in the patients studied by Egoz and Michaeli (4). It has been found that the surgical wound infection rate increases from 1% for operations lasting 30 min to 14% for operations lasting 3.5 h (8).

One of the primary sources of bacterial contamination of wounds during surgery has been operative personnel. Charnley and Eftekhar (2) have shown that bacteria from a surgeon's skin penetrate clean scrub suits and sterile gowns to reach the sterile field. However, difficulty has arisen in trying to document that the organisms generated by the personnel in the operating room are the primary cause of wound infections. In a computer analysis of factors influencing surgical wound infection, Davidson et al. (3) cited the degree of contamination of the wound with microorganisms to be the most important determinant in the development of perioperative infections.

The preferred use of nonwoven barriers for the surgical staff and patient has been well documented (1, 6, 7, 12, 13, 16). Now nonwoven drapes have been developed with a broad-spectrum organosilicon quaternary ammonium antimicrobial agent covalently bonded to the absorbent reinforcement that surrounds the fenestration. This bactericidal fabric should reduce the number of viable bacteria on the surface of the drape. In vitro data have demonstrated this antimicrobial agent to be effective against *Staphylococcus aureus*, *Enterococcus faecalis*, *Escherichia coli*, *Salmonella typhi*, *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, *Candida albicans*, several *Asperigillus* species, *Trichophyton* species, and other potential pathogens (5, 10, 11). Furthermore, the antimicrobial fabric has been shown in the laboratory to be effective against the same series of potential pathogens. The antimicrobial fabric is capable of reducing the number of bacterial CFU recoverable from the fabric by 91% within 15 to 30 min when compared with a nonantimicrobial control fabric (5) (C. Herring, personal communication). The purpose of the present work was to establish the efficacy of the drapes by means of a clinical study and demonstrate that an antimicrobial draping system can reduce the number of potential pathogens surrounding a surgical incision.

## MATERIALS AND METHODS

All of the surgical procedures were performed by the same surgeon in the surgical suites normally used by his service. Clean, clean contaminated, and contaminated surgical procedures were included in the study. All of the procedures allowed appropriate usage of the modified laparotomy drape developed for the study. The surgical cases included in the study varied in length from 0.5 to 6 h. The surgical team wore nonwoven masks, hair covers, and shoe covers. All other wearing apparel and fabrics used on the patient or by the surgical team were closely woven, washed linen.

Preoperative patient preparation included washing the wound site with a standard iodophor scrub solution followed by a standard iodophor prep solution. After the iodophor solution had dried, the special laparotomy drapes were

* Corresponding author.

† Julius Conn died during the preparation of this report. We dedicate this small token of our combined efforts to his memory.

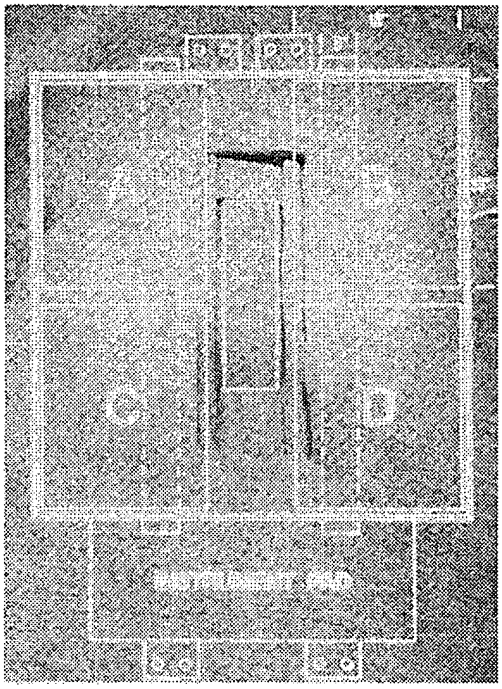

FIG. 1. A standard laparotomy drape reinforcement was modified to consist of four sections (A, B, C, and D), and only two were made of antimicrobial fabric. The locations of the antimicrobial sections were randomly varied. The standard test sections are shown by dotted lines.

placed in the usual manner. The special fenestrated laparotomy drape was the only variable from the routine prepping and draping of the surgical team. (The fenestration is the opening or hole in a surgical drape through which surgery is performed.)

To ensure unbiased sampling, special nonwoven, fenestrated drapes were manufactured for this study by using good manufacturing practices as required by the U.S. Food and Drug Administration. The experimental drapes were standard nonwoven, nonantimicrobial laparotomy drapes on which four 13- by 13-in. (1 in. = 2.54 cm) swatches (A, B, C, and D) of identical-appearing fabric had been attached on the reinforced area surrounding the fenestration (Fig. 1). Two of the swatches were treated with an antimicrobial agent, and two were untreated. Each drape was given a code number, and the locations of the antimicrobial swatches were recorded during the manufacturing process. The positions of the treated and untreated swatches were not known to anyone associated with the study. The positions of the swatches were randomized at the time of manufacturing. The study was conducted by a double-blind protocol. The antimicrobial agent covalently bonded to the treated swatches was 3-(trimethoxysily)propyldimethyloctadecyl ammonium chloride, as used in in vitro studies (5, 10, 11).

At the end of each surgical procedure, standardized 2- by 13-in. patches of swatches A, B, C, and D were aseptically removed from the drape with a clean scalpel and a sterile measuring template. These patches were placed in labeled, sterile, disposable petri dishes. The drape specimens were taken to the microbiology laboratory for immediate processing.

Within 30 min after the operation was completed, each patch was placed into a 250-ml sterile disposable flask containing 75 ml of letheen broth (Difco Laboratories, Detroit, Mich.) adjusted to pH 9.5 with NaOH. Control studies with letheen broth adjusted to pH 7.2 determined that the higher-pH broth did not affect the bacterial survival rate when exposure time was limited as described above. This broth is an accepted neutralizer of the bactericidal activity of quaternary ammonium compounds. The flask was placed on a wrist action shaker and agitated at the highest setting for 15 min. After agitation, the letheen broth was decanted from the flask and filtered through a sterile 0.22-μm (pore size) microporous filter. The filter was then removed and placed on a nutrient pad (Sartorius) in a 50-mm (diameter) petri dish. In some instances, when it was apparent that the letheen broth was highly contaminated, samples of the broth were filtered and counted. This was done to prevent clogging of the filter. The nutrient pad was rehydrated with sterile deionized water containing 1.0% yeast extract. The microbiological specimens were then placed in a humidified incubator at 36°C. The bacterial CFU on the microporous filters were counted and photographed after 72 h of incubation.

Identification of the bacterial isolates was done by standard clinical microbiological techniques. Minitek Enterobacteriaceae II (BBL Microbiology Systems, Cockeysville, Md.), the Staph-Ident system (Analytab Products, Plainview, N.Y.), Sero-STAT Stap (Scott Laboratories, Inc., Fiskeville, R.I.), and the Minitek aerobic gram-positive cocci test (BBL) were used as directed by the manufacturers.

## RESULTS

**Scanning electron micrographs.** To test the antimicrobial characteristics of the treated and untreated fabrics used in this study, we obtained electron micrographs of the fabrics incubated with *E. coli*. These scanning electron micrographs showed that the morphology of bacteria was greatly altered after 15 min of contact with the antimicrobial-agent-treated fabric (Fig. 2B). The same organisms in contact with untreated fabric remained unchanged for at least 2 h (Fig. 2A). The obvious change in bacterial morphology attributed to the antimicrobial fabric is evidence that the bacterial cell wall membrane complex has been disrupted as postulated by Hugo (9) as the mode of action for this class of antimicrobials agent and agrees with the work of Malek and Speier (J. Coated Fabrics 12:38-45, 1982) and Richards and Cavill (14).

**Surgical procedures.** The experimental drape used in this study was a modified, fenestrated, nonwoven laparotomy drape. Therefore, the majority of the procedures involved abdominal incisions. The surgical procedures by general type were as follows: vascular, 35%; liver and biliary tract, 12%; gastrointestinal (including resections, ostomy, etc.), 10%; hernia repair, 9%; miscellaneous (debridement, biopsies, abscess drainage, mastectomies), 34%.

**Bacterial isolation.** One hundred and ten surgical procedures were analyzed during this study. Analysis showed that the bacterial CFU recovered from the drapes divided the surgical procedures into two distinct groups. The groups were determined by the total number of CFU isolated from a single set of drape samples.

In group 1, the bacterial CFU recovered from each case totaled less than 30. Analysis of this group indicated that a comparison of the number of organisms recovered from the antimicrobial portion of the drape versus the CFU recovered from the nonantimicrobial drapes was not statistically relevant. This group was composed of 59 drapes in which the

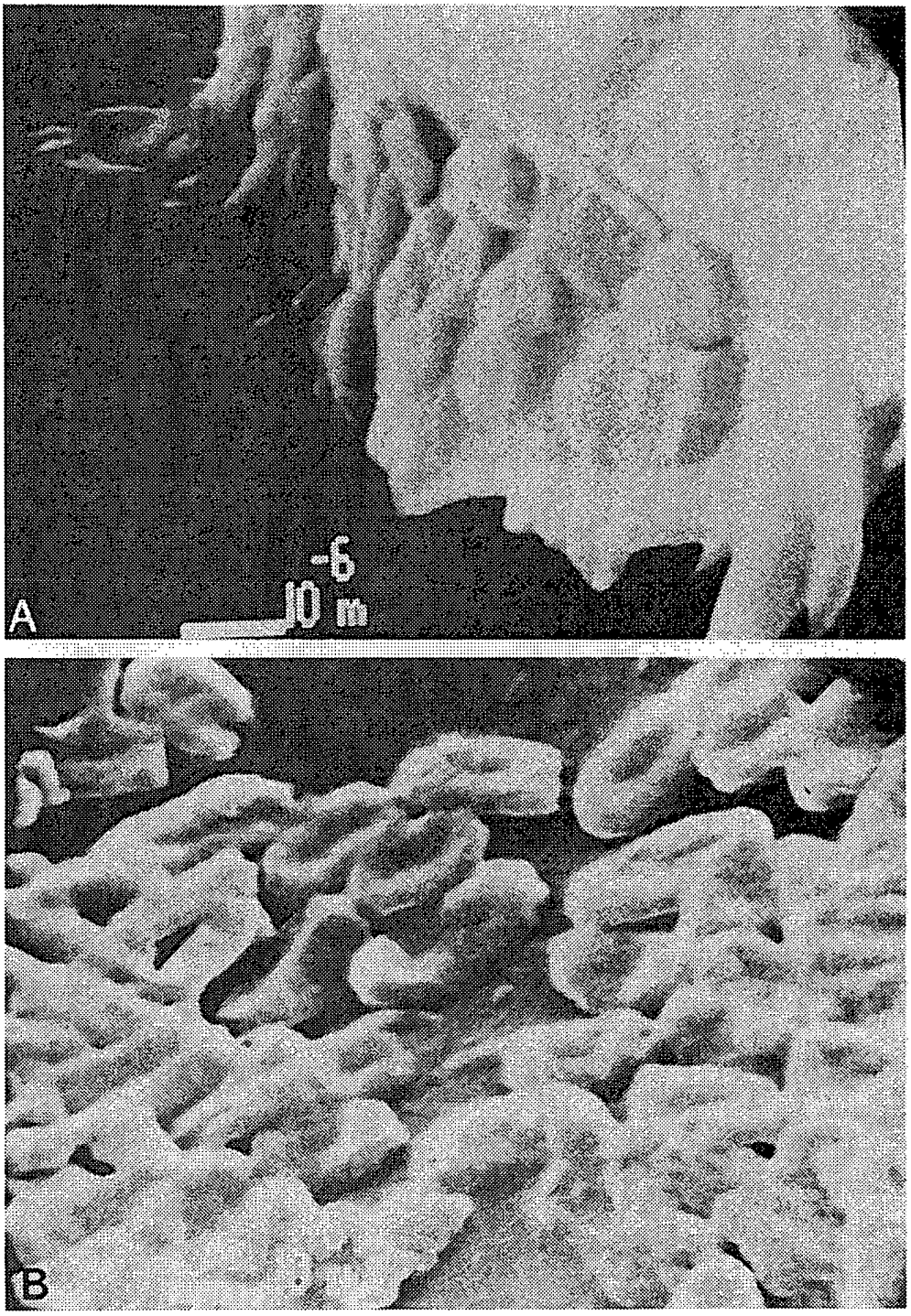


FIG. 2. Scanning electron micrographs of *E. coli* exposed to untreated and antimicrobial-agent-treated fabric (magnification, ×12,000). *E. coli* was suspended in phosphate-buffered water, and portions were placed on appropriate fiber samples. The specimens were incubated at 20°C for 120 min for the control (A) and for 15 min for the antimicrobial sample (B) in a humidified chamber. After incubation, the samples were rapidly vacuum dried and coated with gold. The samples were then examined and photographed with a Cambridge SEM-Stereoscan Mark II. Note the depressed centers of the bacteria on the treated fabric (B) compared with the bacteria on the untreated fabric.

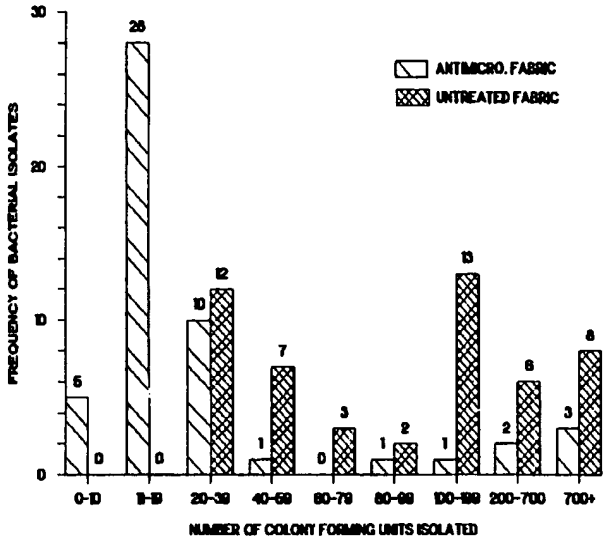


FIG. 3. Distribution frequency of the bacterial isolates recovered from the antimicrobial fabric and untreated fabric swatches from group 2. The actual number of surgical cases in which the indicated number of bacterial isolates recovered from the antimicrobial or untreated swatches is given at the top of each column.

mean number of bacterial isolates from the antimicrobial swatches was 4.5 CFU with a median of 1.9. The nonantimicrobial swatches had a mean bacterial recovery of 7 CFU with a median of 3.1. The range in total CFU was 1 to 29, and the mean length of surgery was 1.8 h with a median of 1.5 h.

Group 2 consists of 51 cases in which more than 30 CFU was isolated. The mean CFU for the antimicrobial swatches was 184 versus 1,172 CFU for the nonantimicrobial swatches. The mean duration of surgery was 3.3 h with a median of 2.9 h. Figure 3 demonstrates the frequency distribution of the bacterial isolates from the antimicrobial and nonantimicrobial swatches. Table 1 lists the numbers of CFU recovered from various locations on the surgical drapes included in group 2.

When each surgical procedure was individually analyzed for bacterial reduction, the bacterial reduction ranged between 15 and 99.9%. The average bacterial reduction percentage was 84.4%. Figure 4 graphically illustrates the bacterial reduction percentage frequency of the surgical procedures in group 2.

Analysis of the actual bacterial recoveries given in Table 1 showed that the data had positive skewness. The skewness is attributable to the clean contaminated and contaminated cases in which exceptionally large numbers of bacteria were isolated (greater than 1,000 CFU).

The surgical procedures from which the greatest number of isolates were recovered all demonstrated high bacterial reduction rates attributable to the antimicrobial fabric. In actuality, the average bacterial reduction percentage for this subgroup of cases was 83%, and the bacterial reduction percentage for the subgroup in which the bacterial isolates were less than 1,000 was 88%.

Bacterial identification was performed on the isolates from 64 cases. Since the organisms killed by the antimicrobial fabric could not be determined, analysis of the percentage of cases from which a particular organism was isolated was performed. Table 2 lists the organisms isolated and identified and the percentage of cases in which that particular bacterium was identified. *S. epidermidis*, *S. hominis*, and *Micrococcus luteus* were the most commonly isolated organisms.

## DISCUSSION

The standard laparotomy drape used in this study had a reinforcement area of 676 $in^2$ surrounding the fenestration. In our study, we sampled four 2- by 13-in. areas (104 $in^2$) located 1.5 in. from the edge of the fenestration for bacterial content after each procedure. Therefore, our sample size was 15.4% of the total area immediately contiguous to the surgical incision site (approximately 2/13 of the reinforcement area). The size of the area analyzed was limited by the method of bacterial isolation used and was as large as practical.

We found that in any fabric some bacteria become trapped in the interstices of the fabric. These bacteria cannot be removed by mechanical agitation. When a known number of bacteria are placed on a fabric, the percentage of bacterial entrapment varies, depending on the fabric. The nonantimicrobial control fabric used in this study normally retains 12 ± 4% of the input bacterial population when the bacterial isolation technique used in this study is used; *i.e.*, approximately 7/8 of the input bacterial challenge was recovered in control studies. Therefore, when the unsampled drape area and expected bacterial entrapment are taken into consideration, it is apparent that the number of bacterial isolates recovered in the study represents only a small portion of the potential pathogens that might be present in the area surrounding the surgical incision. The theoretical total number of bacteria that actually were present in the surgical field at the end of each procedure can be derived from the following formulas: (i) (CFU isolated per procedure/7) 8 = total theoretical bacterial count on the sampled area of the reinforcement corrected for bacterial entrapment; (ii) (CFU [corrected for bacterial entrapment] per procedure/2) 13 = total theoretical bacterial count present on the surgical field at the end of the procedure after corrections for bacterial entrapment and inclusion of the CFU on the unsampled area of the reinforcement.

TABLE 1. CFU recoveries from surgical drapes

| Side of patient | Bacterial recovery (CFU) from: | | | | | | | | % Bacterial reduction attributable to antimicrobial fabric[a] |
|---|---|---|---|---|---|---|---|---|---|
| | Antimicrobial swatches | | | | Nonantimicrobial swatches | | | | |
| | No. | Mean | Range | Median | No. | Mean | Range | Median | |
| Both | 8,025 | 184 | 0–5,000 | 12.5 | 51,586 | 1,172 | 21–20,000 | 105 | 84.4 |
| Left | 3,382 | 78 | 0–2,500 | 3 | 26,240 | 596 | 0–10,000 | 52 | 87.1 |
| Right | 4,643 | 105 | 0–2,500 | 8 | 25,349 | 576 | 0–10,000 | 25 | 81.7 |

[a] Percent reduction = (CFU recovery from nonantimicrobial fabric − CFU recovery from antimicrobial fabric)/CFU recovery from nonantimicrobial fabric.

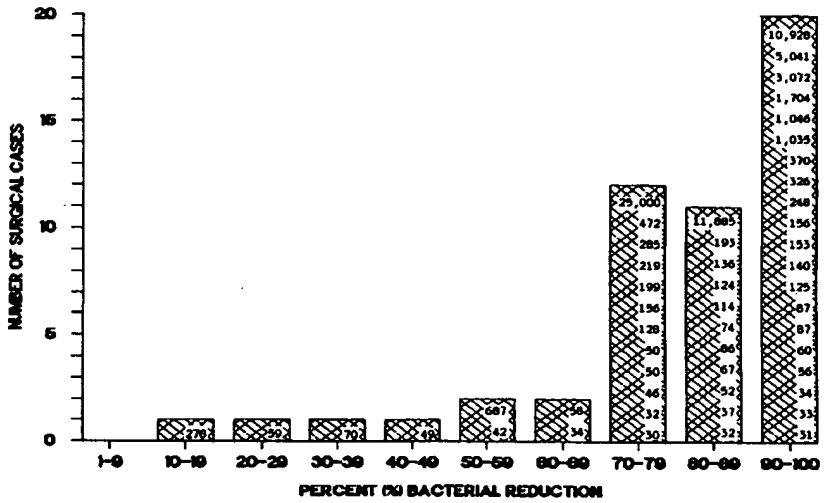


FIG. 4. Bacterial reduction percentage frequency. The individual numbers within each bar of the histogram refer to the actual number of total CFU isolated in the individual procedures analyzed. Each number refers to a single case demonstrating the indicated percentage of bacterial reduction.

These simple mathematical formulations supply a number that reflects the actual potential pathogen population present on the reinforced portion of the drape at the completion of a surgical procedure. The numbers of bacteria in the sterile field derived by using these procedures compared favorably with the bacterial counts found by Sampolinsky in his study on bacterial contamination in a sterile field (15).

Hooten et al. (8) reported that the length of a surgical procedure influences the postoperative infection rate. The differences in the duration of surgery as reflected in group 1 versus group 2 correlated well with their observations. The clinical data demonstrated that, as the time for a surgical procedure increased, the number of bacteria on the surgical field increased.

This double blind in vivo study demonstrated the effectiveness and established the efficacy of an antimicrobial fabric in which a broad-spectrum antimicrobial agent was bonded to the fibers. The antimicrobial fabric reduced the number of potential pathogens surrounding the incision by a substantial margin, independent of the bacterial challenge.

TABLE 2. Percentage of surgical procedures in which specific organisms were identified

| Organism(s) | % of cases in which organism(s) was isolated |
|---|---|
| *S. epidermidis* | 60 |
| *S. hominis* | 53.9 |
| *S. capitis* | 26 |
| *S. haemolyticus* | 26.9 |
| *S. warneri* | 11.1 |
| *S. cohnii* | 4.7 |
| *S. aureus* | 3.2 |
| *Staphylococcus* sp. | 7 |
| *M. luteus* | 39.6 |
| Miscellaneous gram-positive bacilli | 15.8 |
| *Pseudomonas* sp. | 6.2 |
| *E. coli* | 4.7 |
| Miscellaneous gram-negative bacilli | 3.1 |

The antimicrobial fabric was efficacious in clean, clean contaminated, and contaminated cases regardless of the bacterial challenge. No wound infections or adverse healing problems developed in any of the patients. Also, no allergic reactions were seen.

## ACKNOWLEDGMENT

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